

- 1 CABINET FOR HEALTH AND FAMILY SERVICES
- 2 Office of Health Policy
- 3 (Amendment)
- 4 900 KAR 6:125. Certificate of Need annual surveys[, and registration-requirements-for
- 5 new Magnetic-Resonance Imaging units].
- 6 RELATES TO: KRS <u>216B.015</u>, [216B.010, 216B.020(2)(a), 216B.040]
- 7 STATUTORY AUTHORITY: KRS [194A.030, 194A.050,] 216B.040(2)(a)1
- 8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the
- 9 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need
- 10 Program and to promulgate administrative regulations as necessary for the program.
- 11 This administrative regulation establishes the requirements for [registration of Magnetic
- 12 Resenance Imaging units and the requirements for] submission of annual survey data to
- 13 the Cabinet for publication of [that are used-to-produce] annual reports necessary for
- the orderly administration of the Certificate of Need Program.
- Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(6).
- 16 (2) "Days" means calendar days, unless otherwise specified.
- 17 (3)[-"Exempt practitioners" means physicians, dentists, and other practitioners of the
- 18 healing-arts that meet the exemption established in KRS 216B.020(2)(a) and that
- 19 operate a Magnetic Resonance Imaging unit.
- 20 (4)] "Long term care facility" means any entity with licensed long term care beds

- including nursing facility, nursing home, intermediate care, Alzheimer's, intermediate
- 2 care facility for individuals with and intellectual disability, or personal care.
- 3 (4)(5) "Office of Inspector General" means the office within the Cabinet for Health
- and Family Services that is responsible for licensing and regulatory functions of health
- 5 facilities and services.
- 6 (5)(6) Owner" means a person as defined in KRS 216B.015(22) who is applying
- 7 for the certificate of need and will become the licensee of the proposed health service or
- 8 facility.
- 9 (6)[(7)] "Year" means a calendar year from January 1 through December 31.
- Section 2. Entities Completing Surveys. The following entities shall submit annual
- 11 surveys:
- (1) Licensed ambulatory surgery centers;
- 13 (2) Licensed hospitals performing ambulatory surgery services;
- 14 (3) Licensed home health agencies;
- 15 (4) Licensed hospice agencies;
- 16 (5) Licensed hospitals;
- 17 (6) Licensed private duty nursing agencies;
- 18 (7) Facilities with licensed long term care beds;
- 19 (8) Entities that hold a certificate of need for MRI equipment;
- 20 (9) Facilities with megavoltage radiation equipment;
- 21 (10) Licensed psychiatric residential treatment facilities; and
- 22 (11) Facilities with positron emission tomography equipment.
- Section 3. [Entities Completing Surveys on a Voluntary Basis. Exempt practitioners

- 1 that have MRI equipment may submit surveys on a voluntary basis.
- 2 Section 4.] Annual Survey Submission [Including Entities Completing Surveys on a
- 3 Voluntary-Basis]. An annual survey shall be completed for the previous year and
- 4 transmitted electronically by accessing the Office of Health Policy's Web site at
- 5 https://prd.chfs.ky.gov/OHPSurvey/.
- 6 Section <u>4[</u>ξ]. Surveys shall be submitted annually as follows:
- 7 (1) Kentucky Health Survey Registry [2013] Ambulatory Surgery II;
- 8 (2) Kentucky Health Survey Registry [2013] Home Health II;
- 9 (3) Kentucky Health Survey Registry [2013] Hospice;
- 10 (4) Kentucky Health Survey Registry [2013] Hospital;
- 11 (5) Kentucky Health Survey Registry [2013] Private Duty Nursing;
- 12 (6) Kentucky Health Survey Registry [2013] Long Term Care;
- 13 (7) Kentucky Health Survey Registry [2013] Magnetic Resonance Imaging;
- 14 (8) Kentucky Health Survey Registry [2013] Megavoltage Radiation (Linear 15 Accelerator);
- 16 (9) Kentucky Health Survey Registry [2013] Psychiatric Residential Treatment 17 Facility; and
- 18 (10) Kentucky Health Survey Registry [2013] Positron Emission Tomography.
- Section <u>5[6]</u>. Annual surveys shall be completed and submitted no later than March
- 15th of each year. If the 15th falls on a weekend or holiday, the submission due date
- shall be the next working day.
- Section <u>6</u>[7]. Extensions for Survey Submission. (1) A request for an extension for
- submission of data shall be made in writing or via email to the Office of Health Policy.

- 1 (2) The request for an extension shall state the facility name, survey log-in identification number, contact person, contact phone number, contact email address,
- 4 (3) One (1) extension per survey of up to ten (10) days shall be granted.

and a detailed reason for the requested extension.

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- 5 (4) An additional extension shall only be granted if circumstances beyond the 6 entity's control prevents timely completion of a survey.
- Section <u>7[8]</u>. Data Corrections to Draft Annual Reports Utilizing Data Submitted in the Annual Surveys. (1)(a) Prior to the release of a draft report to a facility for its review, the Office of Health Policy shall review data for completeness and accuracy.
- 10 (b) If an error is identified, the facility shall be contacted by the Office of Health
 11 Policy and allowed fourteen (14) days to make corrections.
 - (2)(a) Prior to publication of the reports, the Office of Health Policy shall publish draft reports available only to the entities included in each individual report.
 - (b) Each facility shall be notified of a Web site and provided with a login identification and password required to access each applicable draft report and shall have fourteen (14) days to review the data for errors.
 - (c) Corrections shall be submitted in writing or via email to the Office of Health Policy before the expiration of the fourteen (14) day review period.
- 19 (3)(a) After publication of the reports, reports shall not be revised as a result of data 20 reported to the Office of Health Policy incorrectly by the facility.
 - (b) Corrections received after the fourteen (14) day review period shall not be reflected in the published report.
 - (c) A facility may provide a note in the comments section for the following year's

- report, referencing the mistake from the previous year.
- 2 Section 8[9]. Annual Reports. (1) Utilizing data submitted in the annual surveys, the
- 3 Office of Health Policy shall publish reports annually as follows:
- 4 (a) Kentucky Annual Ambulatory Surgical Services Report;
- 5 (b) Kentucky Annual Home Health Services Report;
- 6 (c) Kentucky Annual Hospice Services Report;
- 7 (d) Kentucky Annual Hospital Utilization and Services Report;
- 8 (e) Kentucky Annual Private Duty Nursing Agency Report;
- 9 (f) Kentucky Annual Long Term Care Services Report;
- 10 (g) Kentucky Annual Magnetic Resonance Imaging Services Report;
- 11 (h) Kentucky Annual Megavoltage Radiation Services Report;
- (i) Kentucky Annual Psychiatric Residential Treatment Facility Report; and
- 13 (j) Kentucky Annual Positron Emission Tomography Report.
- 14 (2) Electronic copies of annual reports may be obtained at no cost from the Office of
- Health Policy's Web site at http://chfs.ky.gov/ohp/dhppd/dataresgal.htm. A paper copy
- may be obtained for a fee of twenty (20) dollars at the Cabinet for Health and Family
- Services, Office of Health Policy, 275 East Main Street 4WE, Frankfort, Kentucky
- 18 40621.
- 19 Section 9[10]. A [Any] facility[, other than an exempt practitioner that has MRI
- 20 equipment, that fails to complete a required annual survey shall be referred to the
- 21 Office of Inspector General for further action which may impact the facility's license
- renewal as provided for in 902 KAR 20:008, Section 2(6).
- 23 Section 10[11. Magnetic Resonance Imaging Equipment Registration on a

- 1 Voluntary Basis by Exempt Practitioners that have MRI Equipment. (1) An exempt
- 2 practitioner who uses a Magnetic Resonance Imaging unit (MRI) may register the MRI
- 3 equipment by disclosing the following information by telephone contact and followed up
- 4 in writing to the Office of Health Policy:
- 5 (a) Name, address, and telephone number of the facility at which each unit is
- 6 located or to-be-utilized;
- 7 (b) Identification of designated contact person or authorized agent of each facility;
- 8 (c) Make, model, and serial number of each unit;
- 9 (d) Date the unit became operational at each site; and
- 10 —— (e) Whether the unit is free-standing or mobile. If the unit is mobile, the submission
- 11 shall also identify the number of days the unit is operational.
- 12 (2) Within thirty (30) days of a change in the facility's address, the addition of
- 13 another MRI-unit, or the discontinuation of any unit, the designated contact person or
- 14 authorized agent shall notify the Office of Health Policy in writing.
- 15 Section 12.] Incorporation by Reference. (1) The following material is incorporated
- 16 by reference:
- 17 (a) "Kentucky Health Survey Registry [2013] Ambulatory Surgery II", screen prints,
- 18 <u>June 2014[2013]</u>;
- 19 (b) "Kentucky Health Survey Registry [2013] Home Health II", screen prints, June
- 20 <u>2014[2013];</u>
- (c) "Kentucky Health Survey Registry [2013] Hospice", screen prints, June
- 22 <u>2014[2013];</u>
- 23 (d) "Kentucky Health Survey Registry [2013] Hospital", screen prints, June

- 1 2014[2013];
- 2 (e) "Kentucky Health Survey Registry [2013] Private Duty Nursing", screen prints,
- 3 <u>June 2014[2013];</u>
- 4 (f) "Kentucky Health Survey Registry [2013] Long Term Care", screen prints, June
- 5 <u>2014[2013];</u>
- 6 (g) "Kentucky Health Survey Registry [2013] Magnetic Resonance Imaging", screen
- 7 prints, <u>June 2014[2013]</u>;
- 8 (h) "Kentucky Health Survey Registry [2013] Megavoltage Radiation (Linear
- 9 Accelerator)", screen prints, June 2014[2013];
- 10 (i) "Kentucky Health Survey Registry [2013] Psychiatric Residential Treatment
- Facility", screen prints, June 2014[2013]; and
- 12 (j) "Kentucky Health Survey Registry [2013] Positron Emission Tomography",
- 13 screen prints, <u>June 2014[2013]</u>.
- 14 (2) This material may be inspected, copied, or obtained, subject to applicable
- copyright law, at the Cabinet for Health and Family Services, 275 East Main Street,
- Frankfort, Kentucky 40621[40601], Monday through Friday, 8 a.m. to 4:30 p.m.

900 KAR 6:125

REVIEWED:

Emily Whelan Parento **Executive Director** Office of Health Policy

APPROVED:

Audrey Tayse Haynes Secretary

Cabinet for Health and Family Services

900 KAR 6:125

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on July 21, 2014, at 9:00 a.m. in Conference Suite B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by July 14, 2014, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until July 31, 2014. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, Phone: 502-564-7905, Fax: 502-564-7573, email: tricia.orme@kv.gov

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 6:125 Contact Person: Diona Mullins (502) 564-9592

- 1. Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes the requirements for submission of annual survey data to the Office of Health Policy.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, 216B.040(2)(a)1.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.040(2)(a)1 by establishing the requirements for submission of annual survey data to the Office of Health Policy for the orderly administration of the certificate of need program.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 216B.040(2)(a)1 by establishing the requirements for submission of annual surveys to the Office of Health Policy
- 2. If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: The regulation has been revised to delete language pertaining to the voluntary registration of MRI equipment and voluntary submission of the Magnetic Resonance Imaging Services Report by exempt practitioners. Also, the amendment incorporates by reference the revised screen shots of the annual surveys.
 - (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to enable the Office of Health Policy to discontinue surveying of CON-exempt MRI services, which have voluntarily reported utilization in the past. Also the annual surveys have been revised to clarify instructions.
 - (c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by updating the required annual surveys for the orderly administration of the certificate of need program.
 - (d) How the amendment will assist in the effective administration of the statutes: This amendment is necessary to enable the Office of Health Policy to discontinue surveying CON-exempt MRI services, which have voluntarily reported utilization in the past. Also the annual surveys have been revised to clarify instructions
- 3. List the type and number of individuals, businesses, organizations, or state and

local governments affected by this administrative regulation: This administrative regulation affects an entity required to submit annual surveys. Approximately 900 entities complete a survey each year.

- 4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Each entity required to submit an annual report shall compete the annual survey online by March 15th of each year.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no charge to complete the survey.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in Question 3: The entities will have updated surveys for collection of 2014 data and will have access to the published utilization reports.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Entities will now have updated surveys for collection of 2014 data.
- 5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
 - (a) Initially: No cost
 - (b) On a continuing basis: No cost
- 6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used for the implementation and enforcement of this administrative regulation will be the Office of Health Policy's existing budget. No additional funding will be required.
- 7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.
- 8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation establishes a \$20.00 fee for a paper copy of the published utilization report. An increase in the fee is not proposed.
- 9. TIERING: Is tiering applied? (Explain why or why not)

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:125 Contact Person: Diona Mullins 502-564-9592

- 1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment may impact any government owned health care facilities which are required to submit annual utilization reports.
- 2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.040(2)(a)1
- 3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
 - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation includes a \$20.00 fee for anyone wishing to purchase a paper copy of an annual report. The fee is necessary to recoup the agency's printing costs incurred in producing paper reports. We anticipate that approximately 40 reports will be purchased for total revenue of \$800.00. The reports are also available electronically at no charge.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation includes a \$20.00 fee for anyone wishing to purchase a paper copy of an annual report. The fee is necessary to recoup the agency's printing costs incurred in producing paper reports. We anticipate that approximately 40 reports will be purchased for total revenue of \$800.00. The reports are also available electronically at no charge.
 - (c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this regulation.
 - (d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this regulation for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

COMMONWEALTH OF KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES Office of Health Policy

900 KAR 6:125. Certificate of Need annual surveys

Summary of Changes to Material Incorporated by Reference

- 1. Annual surveys are required to be completed on-line. Copies of the on-line screens to be used by facilities are incorporated by reference.
- 2. In all surveys, references to specific dates have been deleted to allow the survey tool to be used for any year.
- 3. "Kentucky Health Survey Registry Ambulatory Surgery II" is used by licensed ambulatory surgery centers and licensed hospitals performing ambulatory surgery services to submit annual survey information.
 - Page 4, Definitions-Changed American Hospital Association 2005 Edition to American Hospital Association 2013 Edition.
 - Page 5, Utilization Capacity- Total # operating rooms: Defined as the # of existing operating rooms which currently meet all state and federal requirements (including but not limited to mechanical engineering requirements for temperature, relative humidity, filter efficiency, pressure relationships and ventilation).

The screen prints consist of 9 pages.

4. "Kentucky Health Survey Registry Home Health II" is used by licensed home health agencies to submit annual survey information.

No revisions were made to the questions asked within the survey.

The screen prints consist of 16 pages.

5. "Kentucky Health Survey Registry Hospice" is used by licensed hospices to submit annual survey information.

No revisions were made to the questions asked within the survey.

The screen prints consist of 7 pages.

6. "Kentucky Health Survey Registry Hospital" is used by licensed hospitals to submit annual survey information.

- Page 4, Definitions-Changed American Hospital Association 2005 Edition to American Hospital Association 2013 Edition.
- Page 5, Instructions-Revised language to clarify that Critical Access Hospitals shall complete only Sections B and F.
- Page 5, Service Unit-Inserted new headings "A. Acute Care" and "B. Psych Care".
- Page 6, Service Unit-Inserted new category "F. Critical Access Hosp."
- Page 7, Beds and Utilization by Licensure Category- Added category for Critical Access Hospital Beds.
- Page 7, Instructions-Added instructions regarding verification of the number of OIG licensed beds and how to properly report allocation of general psych beds.
- Page 12, Instructions-Heading changed to Instructions Surgical Services, Lithotripter and CT Services
- Page 12, Instructions- Added instructions for reporting # of existing operating rooms. Total # operating rooms: Defined as the # of existing operating rooms which currently meet all state and federal requirements (including but not limited to mechanical engineering requirements for temperature, relative humidity, filter efficiency, pressure relationships and ventilation).
- Page 13, Cardiac Catheterization Procedure Section-Changed title of report to Kentucky Administrative Claims Data Report-Cardiac Catheterization Report.

The screen prints consist of 17 pages.

7. "Kentucky Health Survey Registry Private Duty Nursing" is used by licensed private duty nursing agencies to submit annual survey information.

No revisions were made to the questions asked within the survey.

The screen prints consist of 9 pages.

- 8. "Kentucky Health Survey Registry Long Term Care" is used by licensed long term care facilities to submit annual survey information.
 - Changed "ICF/MR" to "ICF/IID" throughout the long term care survey.
 - Page 7, Resident Census by Age Group Instructions-Removed 4th bullet which duplicated the 5th bullet.

The screen prints consist of 10 pages.

9. "Kentucky Health Survey Registry Magnetic Resonance Imaging" is used by entities which hold a certificate of need for MRI equipment to submit annual survey information.

No revisions were made to the questions asked within the survey.

The screen prints consist of 8 pages.

10. "Kentucky Health Survey Registry Megavoltage Radiation (Linear Accelerator) is used by facilities with Megavoltage Radiation equipment to submit annual survey information.

No revisions were made to the questions asked within the survey.

The screen prints consist of 6 pages.

- 11. "Kentucky Health Survey Registry Psychiatric Residential Treatment Facility" is used by licensed psychiatric residential treatment facilities to submit annual survey information.
 - Pages 4-6, Psychiatric Residential Treatment Facility Utilization-Under Service Type, added new headings "A. Level I" and "B. Level II".

The screen prints consist of 10 pages.

12. "Kentucky Health Survey Registry Positron Emission Tomography" is used by facilities with Positron Emission Tomography equipment to submit annual survey information.

No revisions were made to the questions asked within the survey.

The screen prints consist of 7 pages.

13. The total number of pages incorporated by reference is 99 pages.